

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Tanya Arenson and David Casimir on 03/02/2010.

The claims are amended as follows:

Amend claim 186 as follows (support found on page 33, lines 16-19):

186. (currently amended) A method of topically treating a human having a Herpes simplex I virus infection, comprising topically exposing a surface of skin or mucosal cells and tissue of a human to a nanoemulsion composition, or a dilution thereof, said nanoemulsion consisting of:

- 1) about 64% by volume discontinuous oil phase;
  - 2) about 22% by volume deionized water[an aqueous phase];
  - 3) about 8%[3-15%] by volume ethanol; and
  - 4) about 5% by volume Polyoxyethylene (20) sorbitan monooleate[3-15% by volume surfactant];
- and
- 5) about 1%[0.5-2% or 1-10%] by volume cetylpyridinium chloride
- such that said nanoemulsion kills said Herpes simplex I virus.

Amend claim 202 as follows (support found on page 33, lines 16-19 and support for EDTA is found on page 5, lines 6, 11,12; page 16, lines 21-24; page 26, lines 13, 20, 21, 25 and 26):

202. (currently amended) A method of topically treating a human having a Herpes simplex I virus infection, comprising topically exposing a surface of skin or mucosal cells and tissue of a human to a nanoemulsion composition, or a dilution thereof, said nanoemulsion consisting of:

- 1) about 5% by volume Polyoxyethylene (20) sorbitan monooleate[3-15% by volume surfactant];
- 2) about 8%[3-15%] by volume ethanol;
- 3) about 64%[50-80%] by volume discontinuous oil phase;
- 4) about 1%[0.5-2% or 1-10%] by volume cetylpyridinium chloride;
- 5) about 22% by volume deionized water[distilled water]; and
- 6) ethylenediaminetetracetic acid

such that said nanoemulsion kills said Herpes simplex I virus.

Cancel claims 193, 194, 200 and 205.

**Reasons for Allowance:**

2. The following is an examiner's statement of reasons for allowance: The primary reason for allowance is the amendment to claims 186 and 202 limiting the composition to the specific embodiment of the composition found page 33, lines 16-19 and the use of "consisting of."
3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

The listing of claims below will replace all previous listings:

1-185. (cancelled)

186. (currently amended) A method of topically treating a human having a Herpes simplex I virus infection, comprising topically exposing a surface of skin or mucosal cells and tissue of a human to a nanoemulsion composition, or a dilution thereof, said nanoemulsion consisting of:

- 1) about 64% by volume discontinuous oil phase;
- 2) about 22% by volume deionized water[an aqueous phase];
- 3) about 8%[3-15%] by volume ethanol; and
- 4) about 5% by volume Polyoxyethylene (20) sorbitan monooleate[3-15% by volume surfactant];

and

- 5) about 1%[0.5-2% or 1-10%] by volume cetylpyridinium chloride

such that said nanoemulsion kills said Herpes simplex I virus.

187-190. (cancelled)

191. (previously presented) The method of Claim 186, wherein said oil phase comprises an oil selected from the group consisting of plant oil, animal oil, flavor oil, mineral oil and motor oil.

192. (previously presented) The method of Claim 191, wherein said plant oil comprises soybean oil.

193. (Cancelled)

194. (Cancelled)

195-198. (cancelled)

199. (previously presented) The method of Claim 186, wherein said composition is formulated in a form selected from the group consisting of a cream, ointment, salve and spray.

200. (Cancelled)

201. (cancelled)

202. (currently amended) A method of topically treating a human having a Herpes simplex I virus infection, comprising topically exposing a surface of skin or mucosal cells and tissue of a human to a nanoemulsion composition, or a dilution thereof, said nanoemulsion consisting of:

1) about 5% by volume Polyoxyethylene (20) sorbitan monooleate[3-15% by volume surfactant];

2) about 8%[3-15%] by volume ethanol;

3) about 64%[50-80%] by volume discontinuous oil phase;

4) about 1%[0.5-2% or 1-10%] by volume cetylpyridinium chloride;

5) about 22% by volume deionized water[distilled water]; and

6) ethylenediaminetetracetic acid

such that said nanoemulsion kills said Herpes simplex I virus.

203. (cancelled)

204. (previously presented) The method of claim 186, wherein said nanoemulsion has a mean particle size of approximately 0.2 to 0.8 microns

205. (Cancelled)

206. (previously presented) The method of claim 202, wherein said nanoemulsion has a mean particle size of approximately 0.2 to 0.8 microns.

Co-pending claims: The examiner is aware of copending claims 1, 2, 5 and 10-13 of 11/928,447 filed Oct. 30, 2007 in which the specific composition of 10-13 (dependent on claim 1) is used to treat conditions herpes simplex virus (claims 2 and 5). The earlier filed claims are allowed to go to issue and the claims of the later filed co-pending application would be addressed as appropriate.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/

Primary Examiner, Art Unit 1618